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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,075	12/17/2003	Perry F. Renshaw	04843/117002	1400

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EXAMINER	
CRANE, LAWRENCE E	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
08/20/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/740,075	RENSHAW ET AL.	
	Examiner	Art Unit	
	LAWRENCE E. CRANE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 8, 2008 (amdt)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7-20 and 22-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7-20 and 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims **4, 6, 21 and 27-30** were previously cancelled, no claims have been amended, the disclosure has not been amended, and no new claims have been added as per the response filed February 7, 2008. No supplemental or additional Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Claims **1-3, 5, 7-20 and 22-26** remain in the case.

Note to applicant: when a rejection or objection refers to a claim **X** at line y, the line number is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **1-3, 5, 7-20 and 22-26** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention; the scope is excessive in view of the disclosed enabling exemplifications.

Examiner has inspected the disclosure and Figures 1 and 2, and finds therein what appears to be data concerning the reactions to the administration of CDP-choline by a single human host, apparently a 33 year old subject who appears to be addicted to or habituated to, alcohol, cocaine and tobacco and who consumes caffeinated beverages, a possible additional habituation. Applicant has claimed broadly the treatment of sleep deprivation in all human and mammalian hosts, but has not provided sufficient exemplifying data to adequately enable such a broad scope of claimed subject matter. Examiner suggests that applicant needs to establish individually the effective treatment of specific sleep related disease conditions (insomnia, narcolepsy, etc. etc.) by testing appropriate groups of subjects (night shift workers, interns doing 24 hour stints, etc.). Alternatively examiner suggests applicant may elect to demonstrate the effective treatment of specific-drug addicted hosts who suffer from sleep deprivation(s). In any event the instant data set is simply inadequate to enable the instant patent claims because of the lack of adequate showing(s) that the claimed effects of CDP-choline administration are common to a reasonable number of similarly situated hosts in need of such treatment.

Because applicant has provided some data, applicant may elect to supply additional data using a declaration under 37 C.F.R. §1.132.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant is referred to the comments following the next rejection.

Claims **1-3, 5, 7-20 and 22-26** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: the breadth of many of the claims is excessive because of the presence of generic terms including "treating a sleep disorder" (claims **1, 12 and 22**) and "increasing cognitive function" (claim **17**).

B. The nature of the invention: the invention is directed to treatment of sleep or sleep-related disorders as defined in claim **13** (substance abuse), in claim **15** (constructive or obstructive sleep apnea, restless leg syndrome, periodic limb movements, narcolepsy), claim **20** (problem sleepiness) and claim **25** (restless leg syndrome, periodic limb movements, narcolepsy).

C. The state of the prior art: the administration of CDP-choline is associated in some prior art references with the effective amelioration of insomnia, particularly in elderly hosts. See the prior art-based rejections below.

D. The level of one or ordinary skill: the level of the ordinary practitioner is variable, because the administration of CDP-choline has been shown herein to be effective in one host, but the remainder of the claimed active ingredients have not been shown herein to have similar activities.

E. The level of predictability in the art: the art of treating sleep disorders is highly variable in its predictability because of the large array of different causes or circumstances

under which it is observed to occur, both known (drugs, shift work, etc.) and unknown (aging, physical injury, etc.).

F. The amount of direction provided by the inventor: referring to Figures 1 and 2, it appears that applicant has only tested the administration of CDP-choline on a single human host who is apparently afflicted with multiple chemical dependencies including to alcohol, cocaine and caffeine.

G. The existence of working examples: there appears to be only a single working example and no clear indication discernable by examiner concerning what particular sleep disorder or disorders where being treated in this particular host.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive in light of the indefinite and functional claim terminology rendering the scope indefinite and because the exemplary evidence is so limited in quantity. As a consequence the minimum necessary guidance concerning how to use the various different active ingredients as listed in claims **1, 12, 17 and 22**, and their application to various different sleep disorder treatments, is simply absent.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Examiner has made minor editorial corrections and additions to the above rejection intended to improve clarity.

Applicant argues that the breadth of the claims is not excessive because the instant disclosure has

" ...provided exemplary embodiments of the individual conditions, numerous compounds to achieve the claimed effects, exemplary doses, formulations and routes of administration of these compounds, exemplary patient populations, sound scientific argument to support the effectiveness of the claimed compounds for the full scope [of the method of treating] as claimed and methods of assessing therapeutic efficacy."

Examiner respectfully disagrees with this analysis for several reasons. First, applicant has only

supplied a single specific embodiment or test subject suffering from multiple problems, not the asserted "patient populations," an assertion that, excepting the single tested host, is entirely prospective. Secondly, the dosages are for the most part prospective, as are the formulations. And lastly, the asserted "sound scientific argument" is also an attempt to advance an excessive extrapolation from what is, in examiner's view, clearly insufficient data. In short the instant disclosure has elements usually associated with a research proposal, not a report of an invention that has been reduced to practice.

Applicant then appears to be arguing that all cited prior art in rejection over art below claim the effectiveness of CDP-choline administration following "... suffering from cerebral injuries," then noting that there had been as many as 6 cited prior art references in previous Office actions. Applicant concludes, without detailed analysis, that "... Applicants have distinguished each of these cited references from the instant claims," and then suggests that the cited art requires exposure to the instant disclosure to establish the relevance thereof, a conclusion that examiner respectfully disagrees with, in the absence of a clear and detailed analysis. In short applicant's argument is both inaccurate and repeatedly conclusory.

Then applicant argues that the level of skill of the ordinary practitioner, particularly a Ph.D. level medicinal chemist or a medical doctor, would have the skill necessary to practice the instant claimed methods of treatment without undue experimentation. Examiner respectfully disagrees because the instant disclosure fails to provide sufficient guidance to permit practice of the instant claimed subject matter without undue experimentation because the specific embodiment, a single host suffering from multiple problems, is on the face of it an insufficient basis to permit the ordinary practitioner, even a Ph.D. medicinal chemist or an MD, to avoid undue experimentation. As noted in *Brenner v. Manson* (148 USPQ 689 (S. Ct. 1966)) a patent is granted for work already accomplished and " ... is not a hunting license."

In the matter of predictability, applicant argues as noted above but without detailed analysis that in effect the instant disclosure provides a sufficient basis for predictability, a conclusion that examiner finds to be inadequately supported by the single specific embodiment.

In the matter of direction provided by the disclosure, applicant asserts that there is direction provided beyond that provided by the single experimental data point. Applicant then

asserts that the prospective disclosure together with the single specific embodiment is sufficient to permit the instant claimed subject matter to be practiced without undue experimentation by the ordinary practitioner. For reason already provided in responses in preceding paragraphs, examiner respectfully disagrees with this assertion.

In the matter of working examples, applicant has argued that the single working example is sufficient, and supports this conclusion with the added assertion that "the Examiner must 'evaluate all of the facts and evidence and state why one would not expect to be able to extrapolate that one example across the entire scope of the claims.'" Applicant by making the above quoted request has attempted to shift the burden to the examiner. In response examiner notes that in medicinally directed claims, the burden is on applicant to provide adequate evidentiary support for the claimed method of medicinal treatment. Applicant is referred to *Ex parte Balzarini et al.* (21, USPQ 2d 1892, 1894 (BPAI, 1991)), a decision standing in its first opinion for the proposition that claims directed to medicinal treatments of diseases in highly unpredictable art areas are properly rejected under 35 U.S.C. §112, first paragraph as lacking adequate enablement, in the absence of sufficient test data in support of the efficacy of the alleged treatment. See MPEP at §2107.03. In earlier Office actions, and again in this Office action, applicant has been and is respectfully requested to supply additional data to demonstrate that the allegations above are properly extrapolated from the single data point provided.

And finally in the matter of whether the level of experimentation required to practice the instant claimed medicinal methods of treatment is undue, applicant again argues in a manner suggesting the the burden is on the Office to adequately support the instant rejection. For reasons of record stated above, examiner respectfully finds this line of reasoning to be unconvincing. Applicant is encouraged to supply additional data to produce a situation wherein there is adequate enabling support for the instant claimed subject matter.

Claims **17 and 22** are objected to because of the following informalities:

In claims **17 and 22** the term "EHNA" is an acronym that is not accompanied by a complete chemical name; e.g. -- 3-azido-3'-deoxythymidine (AZT) --.

Appropriate correction is required.

Claims **1-2, 12-13, 17, 19 and 23** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **1** at line 3 the term "compound comprising" is indefinite because the subsequent list of compounds are all named as separate compounds rather than substituent moieties of a larger molecular species, and because the larger molecular species implied by the term "comprising" (including) is not subsequently defined thereby leaving the metes and bounds of the claimed subject matter incompletely defined. See also claims **12, 17 and 22** wherein the same problem reoccurs.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant has argued that the noted term is appropriate and that the Office has erred. Examiner respectfully disagrees because, when reference is made to a monomeric compound like CDP-choline, the term "comprising" inaccurately suggests that the named compound is accompanied by structural features in addition to those defined by the name "CDP-choline," features that are not defined in the claim thereby rendering the claim incomplete. Examiner respectfully suggests that when referring to monomeric compounds applicant may elect to substitute for the noted term "comprising" narrow-scope language (e.g. the term of art -- consisting of --, -- having the structure(s) --, etc.) to render this rejection moot. Examiner also notes that the instant rejection does not object to the first occurrence of the term "comprising."

In claim **12** at lines 4-5, the term "is not compromised by an existing physical condition" is an improper negative limitation because the particular "existing physical limitation[s]" have not been specified in the claim.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant has argued in opposition to several rejections on the basis applicant's assertion that " ... the Examiner [desires] to have Applicants list every possible existing physical condition (for claim 12) and substance abuse disorder (for claims 13, 19 and 23). A more complete quotation is as follows: " wherein said mammal's health is not compromised by an

existing physical condition," a limitation that is not properly descriptive because one of ordinary skill cannot determine from the claim what existing medical conditions are included within the metes and bounds of the claims and what existing medical conditions are not so included by the instant claims; e.g. does this limitation eliminate all treatment options thereby rendering the claim meaningless?. Applicant is encouraged to specify the particular "existing physical conditions," and presumably the particular prior art references including same, that the instant claim is attempting to avoid.

In claim **13** the term "said sleep disorder is caused by a substance abuse disorder" lacks proper antecedent basis. Examiner suggests introduction of the term -- further comprising -- in order to effectively address this expansion of the subject matter definition of claim **12**. Said term also renders the claim incomplete because the particular "substance abuse disorder" has not been specified. See also claim **23** in re its dependence from claim **22**.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant has argued that the above rejection requires the listing of all possible substance abuses. This argument in response is beside the point of the above rejection which was noting the lack of antecedent basis. One solution to this rejection is straightforward: incorporation of the subject matter of claim **13** in claim **12** and cancellation of claim **13**. Another possibility is simply adding the term of art -- further comprising -- to claim **13** following the term "claim **12**,."

In claim **19** the term "not caused by a substance abuse disorder" renders the claim incomplete because the particular substance abuse disorder(s) has(have) not been specified.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant is referred to the comments following the rejection of claim **12**.

In claim **1** at lines 1 and lines 7-8, the instant claims appears to be self-contradictory because "normalizing the sleep/wake cycle in a mammal" has been alleged in the claim to not include "insomnia." According to Stedman's Medical Dictionary (27th Ed., Lippincott,

Williams & Wilkins, Pugh et al. (eds.), 2000, Philadelphia, PA, see pages 906-907: PTO-892 ref. **X**), "insomnia" is defined as

> "inability to sleep in the absence of external impediments ... during the period when sleep would normally occur; may vary in degree from restless or disturbed slumber to a curtailment of the normal length of sleep or to absolute wakefulness."

In addition applicant is referred to **Beers et al.** (Merck Manual; PTO-892 ref. **W**) wherein the subject of "insomnia" is dealt with in greater detail including medical advise concerning substances well known to be effective in inducing sleep. Examiner does not understand how applicant can justify or otherwise explain the obvious contradiction in terms presented by applicant in claim **1**, and the same or similar contradictions in the remaining independent claims **12, 17 and 22**. The unanswered question is "How can one of ordinary skill effect 'normalizing the sleep/wake cycle' as required by the preamble of claim **1** and not treat 'insomnia' as defined by these two references but as required by the terminal limitation of claim **1**?"

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

Applicant argues that " ... abnormal sleep/awake cycles may be the result of sleeping too much, rather than sleeping too little," suggesting that applicant is prepared to argue against the rejection while failing to provide either additional data to address the underlying weakness of the claims, or to amend the claims to address this and other rejections of record. Applicant also argues that " ... Examiner has provided no reason why all sleep disorders must include insomnia." Examiner has provided within the above rejection a direct quotation from a notoriously well known medical dictionary and medical handbook that constitute portions of an explanation for the rejection. Examiner fails to understand the argument applicant is making because applicant appears to be defending an invention that is not claimed herein. For example there is no claim directed to treatment of oversleeping, treating narcolepsy, or treating students who stay up too late in order to study and therefore voluntarily avoid a normal sleep/wake pattern by force of will. Is applicant arguing in support of treatments that suppress free will? The instant claims do not appear to be directed to the solution of any of these newly discovered

problems, and therefore the arguments advanced by applicant appear to be beside the point and therefore unconvincing.

In claim **1, 12, 17 and 22** the terms "normalizing the sleep/wake cycle," "treating a sleep disorder" (claims **12** and **22**), and "increasing cognitive function in a sleep-deprived mammal" are each insufficient to adequately define the particular disease condition being treated and thereby each noted term renders the associated claim incompletely defined. The above noted terms each represent a description of a therapeutic goal (a sleep-disorder-related symptom to be treated), but said terms do not define with particularity a critical portion of the subject matter (disease to be treated) being claimed.

Applicant's arguments with respect to claims **1-3, 5, 7-20 and 22-26** have been considered but are moot in view of the new grounds of rejection.

In claims **1-3, 5 and 7-11** the claims have described the goals of the treatment (e.g. "normalizing the sleep/wake cycle," etc.) , the claims have described the compounds alleged capable of achieving these goals, but the claims have not provided as assertion of "in need thereof" and the claims have not disclosed that the administration of any one of the listed active ingredients will treat a specific disease condition. Therefore the noted claims are incomplete as method of treatment claims. See also claims **12, 22 and 26** wherein the same problem reoccurs.

Applicant's arguments with respect to claims **1-3, 5, 7-20 and 22-26** have been considered but are moot in view of the new grounds of rejection.

In claims **17** and **20** the method of treating "problem sleepiness," a condition not described with this term in either of examiner's two medical dictionaries or in The Merck Manual, 17th Edition, appears to be synonymous with a method of treating "narcolepsy." Clarification of the intended content of claims **17-20** is respectfully requested.

Applicant's arguments with respect to claims **1-3, 5, 7-20 and 22-26** have been considered but are moot in view of the new grounds of rejection.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy

reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **1-3, 5, 7-20 and 22-26** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***1-16*** of U. S. Patent No. **6,103,703** (PTO-1449 ref. **A10**). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed methods of treatment, directed to "increasing cognitive functions in a sleep deprived mammal, treatment of insomnia, or other cognitive dysfunction" appears to be included partially within the scope of "ameliorating a stimulant induced disorder." In addition the alleged active ingredients are selected from an overlapping list of allegedly active compounds including a cytidine- or 2'-deoxycytidine-5'-nucleotides, are directed to substantially overlapping subject matter. See the **'703** reference at claim ***15*** wherein CDP-choline is specifically noted as a claimed active ingredient.

Applicant's arguments filed February 7, 2008 have been fully considered but they are not persuasive.

The **'703** patent claim ***1*** is directed to "ameliorating a stimulant-induced disorder" and that claim ***13*** therein discloses that one "stimulant" is specifically defined as cocaine. Examiner therefore concludes that "ameliorating a stimulant induced disorder" is overlapping with "treating a sleep disorder" (instant claim **12**) wherein "said sleep disorder is caused by a substance abuse disorder" (instant claim **13**).

Applicant has argued that the **'703** patent "dominates" the instant claims and therefore, citing a definition from the MPEP at §804(II). Examiner respectfully disagrees that the **'703** claims "dominate" the instant claims because the lists of active ingredients are not identical, but do include some overlap. Additionally, the two claim sets are overlapping because the **'703** patent's greater breadth includes disorders not included within the scope of the instant claimed subject matter.

Applicant has also argued that the instant rejection's relies on the term "sleep disorder." The instant rejection supra does not rely on the quoted term so examiner finds applicant's argument to be beside the point.

And lastly applicant disagrees with a comment made in the last Office action's response to this rejection, a subject that examiner has dealt with in the first paragraph of this response.

For the above reasons the instant rejection has been maintained.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **1-3, 5, 7-20 and 22-26** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Renshaw et al. '703** (PTO-1449 ref. **A10**).

The instant claimed methods of treatment include "treating a sleep disorder" including disorder caused by simulants or depressants including "alcohol," "caffeine" and "cocaine," "increasing cognitive functions in a sleep deprived mammal, or other cognitive dysfunction by the administration of a compound selected from extensive listings in claims **1, 12, 17 and 22** wherein these listing all include cytidine, cytidine-5'-nucleotides, a 2'-deoxycytidine-5'-nucleotides including CDP-choline.

The **'703** reference claims the "ameliorating a stimulant induced disorder," wherein the "stimulant" is defined in claim ***13*** as "cocaine" and wherein the treatment comprises administration of a cytosine or cytidine compound including CDP-choline or CDP.

The claimed subject matter in the '**703** reference clearly is not identical with the subject matter in the instant application, but also clearly overlaps therewith in light of the common stimulant and common active ingredients, thereby rendering the instant claimed subject matter obvious.

Therefore, the instant claimed methods of treating sleep-related disorders by the administration of cytosine, cytidine, a cytidylate nucleotide, or CDP-choline to a host in need thereof would have been obvious to one of ordinary skill in the art having the above cited reference before him at the time the invention was made.

Applicant's arguments with respect to claims **1-3, 5, 7-20 and 22-26** have been considered but are moot in view of the new grounds of rejection.

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to

the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
08/17/2008

/Lawrence E. Crane/

Examiner, Art Unit 1623

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